STATE OF MICHIGAN

DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner

v **File No. 121439-001**

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 27TH day of October 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On May 17, 2011, XXXXX, authorized representative of XXXXX (Petitioner), filed a request with the Commissioner of Financial and Insurance Regulation for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. The Commissioner reviewed the request and accepted it on May 24, 2011.

The Commissioner immediately notified Blue Cross Blue Shield of Michigan (BCBSM) of the request and asked for the information it used to make its final adverse determination. The Commissioner received BCBSM's response on June 3, 2011.

Because medical issues were involved, the Commissioner assigned this case to an independent review organization which provided its analysis and recommendations to the Commissioner on June 8, 2011.

II. FACTUAL BACKGROUND

The Petitioner receives group health care benefits from a plan that is underwritten by BCBSM. Her benefits are defined in the BCBSM *Comprehensive Health Care Copayment Certificate Series CMM250* (the certificate).

On November 3, 2010, the Petitioner purchased the prescription drug botulinum toxin to be injected to treat her headaches. The amount charged was $1,304.19.

When the Petitioner sought reimbursement for the drug, BCBSM denied payment, stating it was experimental for treatment of her condition.

The Petitioner appealed the denial. BCBSM held a managerial-level conference on March 8, 2011, and issued a final adverse determination dated March 14, 2011, upholding its denial.

III. ISSUE

Did BCBSM correctly deny coverage for the Petitioner's botulinum toxin prescription?

IV. ANALYSIS

Petitioner's Argument

The Petitioner has experienced daily headaches and severe migraines for years. The botulinum toxin was prescribed by her doctor for treatment of her migraine headaches. Her doctor maintains that use of botulinum toxin "is well within accepted necessary medical practice." Her authorized representative states that botulinum toxin [OnabotulinumtoxinA] has been approved to treat migraines by the Food and Drug Administration.

The Petitioner believes that botulinum toxin injections are medically necessary to treat her migraine headaches and are not experimental or investigational.

BCBSM's Argument

BCBSM argues that botulinum toxin injections for the treatment of migraines are experimental or investigational and therefore are not benefits under the terms of the certificate. The certificate, in "Section 6: General Conditions of Your Contract," contains the following exclusion (p. 6.3):

> **Experimental Treatment**
>
> Services That Are Not Payable
>
> We do not pay for experimental treatment (including experimental drugs or devices) or services related to experimental treatment . . .

"Experimental treatment" is defined in Section 7 of the certificate (p. 7.8):

> Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

BCBSM's "Medical Policy Title: Botulinum Toxins" also states (p. 12):

> The use of botulinum toxins is *experimental/investigational* for the indications listed below, as it has not been scientifically determined to be as safe and effective as conventional treatment:
>
> * * *
>
> - Headaches of any type, including but not limited to cluster, tension, migraine, etc.

BCBSM maintains that its denial of reimbursement was correct because botulinum toxin is experimental or investigational for treatment of the Petitioner's condition.

Commissioner's Review

According to information in the record from BCBSM, this case arose when a request for reimbursement for a prescription of botulinum toxin was denied. However, as apparent from the record, including BCBSM's final adverse determination, the broader issue here is whether botulinum toxin injections are experimental or investigational for treatment of the Petitioner's migraine headaches.

That issue was presented to an independent review organization (IRO) for analysis and a recommendation as required by Section 11(6) of Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO physician reviewer is certified by the American Board of Psychiatry and Neurology, with a specialty in neurology and a subspecialty in neuro-oncology; is a clinical professor of neurology at an east coast university-based school of medicine; and in active practice. The IRO report contained the following analysis:

> **Clinical Rationale for the Decision:**
>
> This enrollee has failed all classes of medication commonly utilized for the prophylaxis of migraine. The frequency of headache and the duration of headache support the use of Botox.[1]

1 "Botox" is a registered trademark for a form of botulinum toxin.

> The standard of care for treatment of chronic daily headaches or any type of migraine occurring four (4) or more days per month is the provision of prophylactic medications. In general, oral prophylactic medications are utilized initially. This enrollee has a diagnosis of chronic daily headaches. This enrollee has been on every class of prophylactic medication (tricyclic antidepressants, calcium channel blockers, beta blockers, serotonin/norepinephrine reuptake inhibitors, and anticonvulsants) utilized in the treatment of migraines, without documented benefit. Botox is utilized as prophylactic therapy in patients with migraines occurring 15 or more days per month lasting four hours per day. Botox is Food and Drug Administration (FDA) approved for the treatment of migraine occurring 15 or more days per month lasting four (4) hours per day. This enrollee has a diagnosis of chronic daily headache, a form of migraine that occurs on a daily basis lasting most of the day. Botox is not experimental for this condition based on its FDA approval. Peer reviewed literature reflects the standards of care as documented above.
>
> Again, this enrollee has failed multiple oral agents and meets criteria for Botox as detailed in the medical literature. The current standards of care as practiced in the Neurology community, as well as the current body of peer-reviewed medical literature, support the use of Botox in this clinical scenario.
>
> **Recommendation:**
>
> It is the recommendation of this reviewer that the denial of coverage issued by Blue Cross Blue Shield of Michigan for Botox injections be overturned.

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner accepts the conclusion of the IRO and finds that botulinum toxin injections are not experimental for treatment of the Petitioner's migraine headaches.

V. ORDER

Blue Cross Blue Shield of Michigan's final adverse determination of March 14, 2011, is reversed. BCBSM shall cover the Petitioner's botulinum toxin within 60 days of the date of this Order and shall, within seven (7) days of providing coverage, furnish the Commissioner with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.